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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,204	06/22/2001	Moshe Fleshner-Barak	1662/53002	7559

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EXAMINER	
FUBARA, BLESSING M	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 10/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/887,204	FLESHNER-BARAK ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-112* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *90-96* is/are allowed.

6)☒ Claim(s) *1-89 and 97-112* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *01/24/02,03/08/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of applicants' response Pre-Exam formalities notice , declaration and petition filed 12/15/03; IDS filed 01/24/2002, 03/08/2003, 09/17/2002 and 03/21/2003.

Priority

This application claims the benefit of provisional applications 60/213,832, 60/217,110 and 60/223,212 filed 06/23/2000, 07/10/2000 and 08/04/2000 respectively.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-33 and 35-82 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-42 of U.S. Patent No. 6,476,006. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims encompass the claims of 6,476,006 and the comprising language allow the presence of the therapeutic agent recited in issued claim 1.

3. Claims 1-33 and 35-82 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-42 of copending

Application No. 10/420,403, published as US 2003/0203878. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims encompass the co-pending claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. Claims 1-33 and 35-82 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-38 of copending Application No. 10/196,766, published as US 2003/0158154. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims encompass the co-pending claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claims 1-33 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7, 32-39, 41-50 of copending Application No. 10/026,573, published as US 2002/0147208. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims encompass the co-pending claims and the comprising language of examined claim 1 encompasses the presence of iritonecan in copending claim 7.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-7, 9-14, 19-31, 35-38, 40-50, 52-82 and 97 are rejected under 35 U.S.C. 102(e) as being anticipated by Curatolo et al. (US 2002/0006443 A1).

Curatolo discloses a tablet or capsule or particulate composition that comprises active agent, sodium starch glycolate or croscarmellose sodium, tannic acid, hydroxypropymethylcellulose and hydroxypropylcellulose (paragraphs [0043], [0029], [0049], [0050], [0059], [0085], [0088], [0095], [0096], [0090], [0105], [0110], [0114]; the tablet is multi-layered (paragraph [0029]) and coated (paragraph [0043]). The instant dispersion is not directed to the molecular dispersion excluded by Curatolo (see paragraph [0031]. Future intended use is not critical in a composition claim. "Contacting gastric fluid" is a future intended use and does not limit the composition. Expansion of the composition or vehicle when placed in contact with a gastric fluid is a property of the vehicle/composition and the property of the composition or vehicle cannot be separated from the composition/vehicle. Curatolo meets the limitations of the claims.

8. Claims 83-85, 99-101 are rejected under 35 U.S.C. 102(e) as being anticipated by Wong et al. (US 6,342,249).

Wong discloses a sustained release and pulse release dosage forms (column 8, line 1; column 25, lines 3-11 and 19-35; column 26, lines 1 and 3; and column 33, line 13) that comprise drugs and few of the drugs that can be delivered by the dosage form are methylphenidate and levodopa (column 12, lines 13 and 35), hydroxypropylmethylcellulose or hydroxypropylcellulose and mixtures of hydroxypropylmethylcellulose and hydroxypropylcellulose (column 3, line 26; column 10, line 63, column 7, lines 47-55; column 19, lines 30-50; column 21, lines 44-63; column 26, lines 39, 40, 43, 44, 66, 67; column 27, line 27; and column 29, lines 52, 61 and 65). The dosage form is layered (Figures 3 and 4) and comprises particles (abstract, column 2, line 65 to column 3 line 32). Claim 83 is directed to sustained release formulation that comprises levodopa. Dependent claim 86 defines the matrix materials or excipients. Claims 84 and 85 define the properties of the dosage form and the property is inherent to the broad dosage form and cannot be separated from the dosage form. Wong administers the composition to a subject in need thereof just as the instant method and the composition will inherently perform the functions claimed in claim 99 after administration. Wong meets the limitation of the claims.

9. Claims 102-104 are rejected under 35 U.S.C. 102(b) as being anticipated by Swanson et al. (US 4,326,525).

Swanson discloses a method of administering a dosage form where the method comprises orally administering methylphenidate containing dosage form Column 2, lines 59 and 60) and the dosage form contains methylphenidate (column 7, line 16), tannic acid (column 7, line 44;

column 8, line 16). The method of claim 102 is an administration of methylphenidate and the prior art administers the same methyphenidate formulation. No specific dose is claimed and the prior art meets the limitations of the claims as the methylphenidate the prior art would perform the same function as the methylphenidate of claim 102. The claim does not recite auxiliary agents or amounts/dose of the methylphenidate that would distinguish the claim form the prior art. Swanson meets the limitation of the claims.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 8, 15-18 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Curatolo et al. (US 2002/0006443).

Curatolo is discussed above. Curatolo differs from the claims by not disclosing the amounts recited in the designated claims. However, differences in concentrations will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). There is no demonstration in the specification showing that the recited amounts provide unusual results. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare composition of Curatolo. One having ordinary skill in the art would have

been motivated to incorporate the proper amounts of the auxiliary agents with the expectation of providing sustained release of the actives.

12. Claims 86-89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al. (US 6,342,249).

Wong is discussed above. Wong differs from the claims by not disclosing the amounts recited in the designated claims. However, differences in concentrations will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). There is no demonstration in the specification showing that the recited amounts provide unusual results. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the levodopa or methylphenidate composition of Wong. One having ordinary skill in the art would have been motivated to incorporate the proper amounts of the auxiliary agents with the expectation of providing sustained release of the actives.

13. Claims 22, 34, 35, 97, 98 and 105-112 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al. (US 6,342,249) in view of Swanson et al. (US 4,326,525).

Wong discloses a composition comprises levodopa or methylphenidate, superdisintegrant and hydroxypropylmethylcellulose or hydroxypropylcellulose and mixtures of hydroxypropylmethylcellulose and hydroxypropylcellulose as discussed above. Wong fails to add tannic acid to the composition. However, Swanson as described above discloses methylphenidate composition that contains tannic acid and both prior art references administer

the formulation to a subject in thereof. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the methylphenidate composition of Wong. One having ordinary skill in the art would have been motivated to modify the composition of Wong by adding the tannic acid of Swanson as part of the buffering system for the formulation.

Claims 90-96 are allowable because the prior art does not disclose a composition that comprises methylphenidate, tannic acid and superdisintegrant.

Other Matters:

Claim Rejections - 35 USC § 112

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claims 88 and 97 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Averting in claim 97 is not clear. How is the disease averted?

It is not clear where "embedded in shell..." fits in the composition. To expedite prosecution, the "embedded in shell..." is considered to be part of the composition and not accorded to the optional components. Clarification is respectfully requested.

Election/Restrictions

More inventions than 1 are claimed. An effort is made at examining the entire claims in order to expedite prosecution. However, applicants may consider electing a specific invention for continuation of the prosecution.

For example:

A. The process of making the orally administrable composition as recited in **claims 108-112** is made by a process other than the recited process and these claims are not related to the compositions claims that contain tannic acid and specific drugs.

B. The method claims, 97-101 differs from

C. The method claims 102-107

D. Claims 1-21 does not contain tannic acid

E. Claims 22-82 contain tannic acid and the method claims 97-99 depend form claim 22.

F. Claims 83-89 are directed to levodopa

G. Claims 90-96 are directed to methylphenidate

Applicants' cooperation is respectfully requested.

16. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification and in the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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